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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,558	09/14/2001	Keiko Matsumoto	P 0283675	7124

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EXAMINER	
PULLIAM, AMY E	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 02/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/936,558	MATSUMOTO ET AL.	
	Examiner	Art Unit	
	Amy E Pulliam	1615	

-- Th MAILING DATE of this communication appears on the cov r she t with th corr spond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Papers

Receipt is acknowledged of the Preliminary Amendment A, the Change of Address and the Supplemental Information Disclosure Statement, received by the Office September 14, 2001, June 26, 2002 and August 12, 2002, respectively.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 6, 7, 9, 10, 14, 17, and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims, as written, are very wordy and difficult to interpret. The examiner has interpreted claim 1 to require a powder comprising an active, alone or in combination with a diluent, and a surfactant. As an example, for claim 1, the examiner recommends language such as : "A surface modified powder comprising an active agent, a surface modifying material, and optionally a diluent, wherein the powder has a flowability which enables direct tableting." Claims 2 should be similarly worded.

Claim 6 might be worded "the surface modified powder of claim 5, comprising 0.1 to 5 wt % light silicic anhydride."

Additionally, in claim 9, it is very unclear what is being claimed. Recommended language is: "The surface modified powder comprising an active agent and a diluent selected from the group consisting of finely divided titanium oxide, talx, erythritol, and trehalose,

wherein said powder is subjected to dry coating. [However, it is pointed out that this a product claim, and a process limitation does not render patentable weight to the claim, unless specific coating components are included in the claim.]

It is also recommended that claims 2-10 begin with "the surface modified powder according to claim 1" (or 5 for claim 6) rather than "the surface modified powder comprising a pharmacologically active agent according to claim 1." This makes the claim less wordy and more clear. Particularly because claim 1 is drawn to the whole powder, not the active agent.

These are just examples, as each of claims 1, 2, 6, 7, 9, 10, 14, 17, and 18 is considered confusing by the Examiner. It is recommended that Applicant reword the claims so they are more easily understood. Any amendments are greatly appreciated.

Claims 15 and 16 provide for the use of the surface modified powder, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 15 and 16 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for

example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 7, 9-14, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by GB 1,480,175. This reference discloses a pharmaceutical preparation in the form of coated tablets prepared by the direct compression of an active, wherein the composition can further comprise a lubricant, such as talc, magnesium stearate or stearic acid, an adjuvant, such as lactose or anhydrous calcium phosphate, and a disintegrant, such as starch.

Claims 1-14, 17, and 18 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 10114655 (abstract). The reference discloses a pharmaceutical preparation, comprising a medicine, an additive and disintegrating agent. More specifically, the reference teaches that the excipient can be a salt of silicic acid, and the disintegrant can be crospovidone. Additionally, the IPER teaches that the reference teaches the use of lactose as an excipient, and specifically powdered anhydrous silicic acid as a lubricant (page 2, upper right column, line 16 – lower left column, line 6). The reference also teaches that the formulation is rapidly disintegratable. Therefore, the teachings of this reference anticipate applicant's instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-14, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over GB1,480,175, as discussed above, and in view of the following. The reference is discussed above as anticipating several of Applicant's claims. The reference does not specifically teach the use of silicic anhydride as the lubricant, nor does it specifically discuss the angel of repose. Regarding the silicic anhydride, it is the position of the examiner that one of ordinary skill in the art would know that silicic anhydride is an acceptable equivalent for the likes of talc and magnesium stearate. The selection of a known material based on its suitability for its intended use is obvious absent a clear showing of unexpected results attributable to the applicant's specific selection. Furthermore, regarding the angle of respose, the Office does not have the facilities for examining and comparing applicant's product with the product of the prior art in order to establish that the product of the prior art does not possess the same material structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is upon the applicant to prove that the claimed products are functionally different than those taught by the prior art and to establish patentable differences. *See Ex parte Phillips*, 28 U.S.P.Q.2d 1302, 1303 (PTO Bd. Pat. App. & Int. 1993), *Ex parte Gray*, 10 USPQ2d 1922, 1923 (PTO Bd. Pat. App. & Int.) and *In re Best*, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977).

Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Claims 1-14, 17, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 10114655, as discussed above, and in view of the following. The reference, as discussed above teaches a fast disintegrating tablet composition comprising the same components claimed by Applicant. First, the reference does not teach each and every one of the examples of excipients claimed by Applicant. However, the reference does teach at least one of each type of the claimed excipients. Furthermore, there is nothing specific in the abstract discussing the method of making the formulation. However, based on the broad language in Applicant's claim, it is the position of the examiner that the reference is suggestive of the basic method of blending powders together prior to direct compression to formulate a tablet. One of ordinary skill in the art would have been motivated to use this method to create a fast disintegrating tablets, using the specified materials. Therefore, this invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy E Pulliam whose telephone number is 703-308-4710. The examiner can normally be reached on Mon-Thurs 7:30-5:00, Alternate Fri 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on 703-308-2927. The fax phone numbers for the

organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A. Pulliam
Patent Examiner/ AU 1615
February 6, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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